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ALLIANCES IN MEXICO  
AND SRI LANKA

March 30, 2021

**VIA ECF**

The Honorable Robert Kugler  
Senior United States District Court Judge  
District of New Jersey

The Honorable Karen M. Williams  
United States Magistrate Judge  
District of New Jersey

The Honorable Thomas Vanaskie  
Special Master  
Stevens & Lee

**Re: In re Valsartan, Losartan, and Irbesartan Products Liability Litigation  
Case No. 1:19-md-02875-RBK-JS**

Dead Judges Kugler, Williams, and Vanaskie:

This letter is to provide Defendants' positions with respect to the topics remaining on the agenda for the conference with the Court on March 31, 2021. Defendants have not added any new agenda items since last week's agenda submission, but in some instances Defendants' position statement has been updated to reflect the latest developments.

**1. Defendants' Request for Guidance Regarding Dismissal of Certain Cases Pursuant to Motion to Dismiss Order No. 5**

As set forth in Defendants' agenda statement last week, Defendants seek the Court's guidance on the viability of Plaintiffs' claims that were dismissed with prejudice via the Court's Motion to Dismiss Order No. 5 (Order No. 5) (ECF 839). In Order No. 5, the Court granted

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Defendants’ Motion to Dismiss, in part, and dismissed, with prejudice, all claims arising under Louisiana law, as subsumed by the Louisiana Products Liability Act (LPLA), and all claims under the New Jersey Consumer Protection Act. These dismissals with prejudice apply to all of the claims asserted in complaints filed individually by approximately 39 Louisiana plaintiffs.<sup>1</sup> Thus, the dismissal of those complaints is final, and they may not be revived by amendment under Fed. R. Civ. P. Rule 15. *See Smith v. Kershentsef*, No. 19-3893, 2021 WL 400148, at \*2 (3d Cir. Feb. 4, 2021) (explaining that dismissal with prejudice is final judgment on the merits); *Petrossian v. Cole*, 613 F. App’x 109, 111 (3d Cir. 2015) (“A dismissal with prejudice constitutes an adjudication on the merits ‘as fully and completely as if the order had been entered after trial.’”); *see also Suddreth v. Mercedes-Benz USA, LLC*, CA No. 10-cv-05130, 2012 WL 13034279 (D.N.J. July 31, 2012) (noting that dismissal with prejudice is final judgment barring amendment under Rule 15).

Defendants request the Court’s guidance as to whether another order dismissing the Louisiana complaints by caption is necessary. Defendants find it necessary to seek immediate guidance on this issue, as five of the Louisiana cases were selected for the initial bellwether pool of 28 cases prior to the Court’s dismissal ruling and this issue directly impacts the discussion of the Bellwether processes discussed below. *See* Tr. 2/24/21 CMC, 60:1-3 (THE COURT: “we lost some bellwether cases because of the Court’s – one of the Court's motions to dismiss decisions.”).

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<sup>1</sup> Each Louisiana Personal Injury plaintiff was required to file a Short Form Complaint where they were allowed to select the causes of action they allege from a provided list. Included in the list was: “Other State Law Causes of Action as Follows:” where a plaintiff could have listed a cause of action under a state’s PLA; no Louisiana plaintiff listed in the Proposed Order chose to select that option and bring a cause of action under the LPLA.

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Defendants first invited Plaintiffs to meet and confer on this issue, or to provide their views, and then informed Plaintiffs that Defendants intended to seek the Court's guidance on this issue. *See* Goldberg emails dated 3/22/21 and 3/21/20, attached as Ex. A. The parties conferred on this issue on March 29, 2021 without resolution. The issue is of immediate concern because five of the twenty-eight bellwether pool plaintiffs are impacted. Three of the five were Defendants' picks, while two of the five were Plaintiffs' picks. As Defendants made exceedingly clear, Defendants have no ulterior motive of reforming the bellwether pool; after all the majority of the impacted Plaintiffs were *defense* picks. Defendants, however, do not want to waste resources taking discovery of bellwether plaintiffs whose claims have been dismissed with prejudice and are no longer viable, as Defendants believe. Likewise, Defendants do not want to release any of the current bellwether pool plaintiffs if there is a possibility their claims can be revived through amendment, as Plaintiffs argue.

## **2. Bellwether Trial Pool Order**

Defendants seek entry of the attached proposed Draft Order Establishing Trial Pool ("Draft Order") (attached as Ex. B), which memorializes the parties' agreement regarding the initial Bellwether process. As discussed at the February 24, 2021 Case Management Conference, the parties met and conferred over a process for selection of plaintiffs for a Bellwether Trial Pool. By agreement, on January 15, 2021, counsel for each side simultaneously disclosed fifteen (15) personal injury plaintiffs for inclusion in the Bellwether Trial Pool. The parties' respective disclosures are attached as Exhibits C and D. Plaintiffs and Defendants disclosed two of the same picks (as a result of the Parties' compromise to choose five selections from **Plaintiffs'** original pool of DFS-request Plaintiffs), resulting in a total of twenty-eight (28) cases in the Bellwether

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Trial Pool. Subject to the Court's approval, the parties have memorialized these selections in the attached proposed Draft Order Establishing Trial Pool ("Draft Order") (Ex. B).

The parties have agreed as to the language of the Draft Order, except for the dismissal provision of paragraph 7, which remains in dispute. Previously, Defendants had proposed a draft order that stated: "Bellwether Trial Pool cases may be dismissed only by court order, on terms that the Court considers proper. In the event this Court permits a Bellwether Trial Pool case to be voluntarily dismissed, the Party who selected that case for the pool may pick a replacement case from the entirety of the personal injury cases filed in or transferred to the MDL." Plaintiffs' only objection to the proposed language was the provision requiring court approval for voluntary dismissals. Plaintiffs joined in Defendants' proposal that dismissed Bellwether pool cases be replaced by the party who selected that case. Plaintiffs stated specifically in their February 23, 2021 CMC submission:

The Parties have held productive meet and confer sessions to discuss issues associated with the entry of a Bellwether order. **With respect to this order, the only remaining dispute between the parties concerns dismissal procedures for Bellwether cases. Defendants suggest that Bellwether cases may only be dismissed by court order on terms that the Court considers proper.** Plaintiffs believe this language is unnecessary. In the Benicar litigation, cases were selected for the bellwether pool by random selection. There, the Court allowed bellwether cases to be dismissed and to be replaced again by random selection. Here, the parties have each selected a set of cases for work-up. **Thus, Plaintiffs propose that if a Bellwether case is dismissed, the party who selected that case for the pool may pick a replacement. This procedure would allow Defendants to re-select a case for the pool if a case in their original selection is dismissed, thereby alleviating the concern that dismissal of a case in the Defendants' set would upset the balance of the pool.**

See Pl's CMC Submission, dated February 23, 2021 at p. 3 (Ex. E) (emphasis added). Following the Court's guidance at the February 24, 2021 CMC, and instruction to the Parties to continue

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conferring on the language of the proposed order, Defendants removed the language requiring court approval for voluntary dismissals and resubmitted the draft to Plaintiffs. *See* Tr. 02/24/21 CMC at 69:6-8.

Defendants' current proposed order states: "If a Bellwether Trial Pool Case is dismissed, the Party who selected that case for the pool may pick a replacement from the entirety of the personal injury cases filed in or transferred to the MDL. Replacement cases should be picked no less than four months prior to the operative deadline to complete the second phase of fact discovery or by other deadline by consent of the parties or court order. *See* [CMO No. 23](#), dated 2/11/21." As cited above, this language is entirely consistent with Plaintiffs' proposal that **"if a Bellwether case is dismissed, the party who selected that case for the pool may pick a replacement."** *See* Pl's CMC Submission, dated February 23, 2021 at p. 3 (Ex. E). Defendants' proposed order simply adds a timeframe for the replacement of the cases, to ensure there is enough time to conduct discovery in the cases prior to discovery deadlines. Defendants are fully willing to meet and confer over the exact time period for replacement picks but have not received any reaction from Plaintiffs to the timing provision.

After not receiving consent from Plaintiffs to the revised proposed Order, the parties met and conferred on March 22, 2021. Despite unequivocally agreeing with party-selected replacement picks at last month's CMC, Plaintiffs inexplicably reversed position on the method for replacement picks, now arguing that replacements are not needed for the pool of twenty-eight, or if they are replaced, it should be by random selection. Thus, even though Defendants revised paragraph 7 to comply with the Court's guidance, Plaintiffs continue to object to the language of paragraph 7 and will not agree to the Order documenting the parties' efforts to date.

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Plaintiffs' reversal of position regarding dismissals and replacement picks, seems to be driven by the recognition that their new proposed Bellwether Trial Plan, discussed below, is wholly inconsistent with the Parties' negotiations, agreements and representations to the Court to date. The Court's scheduling order, set forth in [CMO 23](#), entered on February 11, 2021, provides that ten of these twenty-eight Plaintiffs will be deposed by June 1, 2021, with the remaining Plaintiffs and Plaintiff-specific fact discovery to be completed by October 4, 2021. Defendants are in the process of scheduling these Plaintiff depositions, with depositions currently scheduled on April 13, 20, and 28. Regardless of the process for any further winnowing of the trial pool prior to trial, which should be subject to further meeting and conferring, an Order memorializing the initial selection process, and a provision for replacement of dismissals, needs to be entered without further delay.

### **3. Plaintiffs' Newly Proposed Bellwether Trial Plan**

As a preliminary matter, Defendants believe it is premature for the Court to rule upon Plaintiffs' newly proposed Bellwether Trial Plan, given the parties have had limited opportunity to meet and confer over the proposal and there is no immediate need for finalizing a complete trial sequencing process. Nonetheless, because Plaintiffs have raised this with the Court now, Defendants will address Plaintiffs' newly proposed plan.

Despite progress made to date, now in what can only be interpreted as an attempt to reduce Plaintiffs' discovery burdens, on March 3, 2021, Plaintiffs sent Defendants a letter proposing a "Bellwether Trial Plan," which attempts to undo the parties' progress in fashioning a reasonable Bellwether plan to date. As reported the Court at the CMCs on January 27, 2021 and February 3, 2021, and the Parties worked diligently to agree on the process that resulted in a pool of twenty-eight Plaintiffs for case specific work-up. Now, apparently realizing that the Court's CMO 23

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allows Defendants to proceed with taking the depositions of these twenty-eight Plaintiffs and Plaintiff-specific third-parties by October 4, 2021, Plaintiffs are scrambling to prematurely reduce the number of bellwether pool Plaintiffs, so that they do not have to conduct this discovery. But Plaintiffs' proposed Bellwether Trial Plan raises a number of practical concerns, as well as potential prejudice to Defendants.

Plaintiffs' newly proposed plan provides that the pool of 28 bellwether cases would be winnowed to just eight via random selection, following the completion of Plaintiff depositions, and no other discovery. Prior to receiving this letter, Defendants' understanding, based on a reasonable reading of [CMO 23](#), was that all 28 cases in the Bellwether Trial Pool would proceed through Plaintiff-specific fact discovery. Presumably, in the meantime the Parties would meet and confer on a process for further winnowing and sequencing the cases for trial, once the Parties had more information about these cases.

Accordingly, Defendants responded to Plaintiffs' new proposal, objecting to the winnowing of the pool at this early stage and setting out their position that such discussions are premature. *See* Letter from Ms. Lockard to Mr. Williamson, dated March 19, 2021 (attached as Ex. F). Defendants noted that they do not oppose a winnowing of the Bellwether Trial Pool at a later stage, after sufficient discovery is completed for the Parties to more accurately assess the strengths and weaknesses of the cases and their representativeness of the cases in the overall pool. Though Defendants believe it is premature to present an alternative proposal for winnowing, at a minimum Defendants' counterproposal would incorporate the following concepts:

1. Allow for the completion of some degree of Plaintiff-specific discovery on the 28 agreed Bellwethers prior to the next stage of winnowing;
2. Allow the Parties some input into the selections, or strikes, taking into account

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the discovery obtained;

3. Result in a final Bellwether set of more than 8, perhaps as many as 12 or 14, to be randomly sequenced by the Court for trial given the number of Defendants and distribution scenarios that are involved; and
4. So-called “joint picks” should not automatically be included in the winnowed trial pool set.

First, Plaintiff-specific discovery of these twenty-eight agreed Plaintiffs should proceed according to the terms of [CMO 23](#), and second, the Parties should be allowed subsequent input in a further winnowing to ensure representative cases remain in the pool. To date, Defendants and the Court know very little about these cases, as medical records and Plaintiff’s Fact Sheets are still being provided and updated. As Defendants have pointed out, discovery may reveal certain cases in the Bellwether Trial Pool are not appropriately representative trial cases. For example, depositions of treating physicians may reveal that certain cases involve idiosyncratic Plaintiff-specific issues. Discovery will allow the Parties to better identify which of these twenty-eight cases are appropriate trial candidates, and reduce that number to a manageable set to be sequenced for trial.

While Defendants are open to further negotiations over the amount of discovery that should be allowed as to each of the twenty-eight Plaintiffs prior to the next stage of winnowing, Defendants believe at a minimum they should be allowed to take Plaintiffs’ depositions and the depositions of their key prescribers and treaters. Defendants are willing to consider a reasonable limitation on the number of treating physician depositions (for example, two to three for most cases absent good cause shown for more). Plaintiffs indicated, though, that they oppose **any**



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depositions beyond Plaintiff depositions prior to a winnowing of the pool, and therefore are unwilling to consider compromise proposals.

Third, Defendants believe the ultimate trial pool needs to be larger than eight cases in order to provide a panel of cases that adequately represents a sufficient array of Defendants and distribution chains, given the large number of finished dose manufacturers, API suppliers, and downstream Defendants in this litigation. Unlike a single-defendant MDL, such as Benicar (where there were ten final bellwether trial plaintiffs), this litigation warrants a slightly larger pool, which could then be randomly sequenced by the Court for trial.

Moreover, there will likely be some natural winnowing of the pool of twenty-eight over the course of discovery. Both Parties recognize that as discovery progresses, some cases may be dismissed, either voluntarily or by Court order. (For example, the Court's [Order No. 5](#) on Defendants' Motion to Dismiss holding that all Louisiana Plaintiff claims are subsumed by the Louisiana Products Liability Act, could result in the loss of at least five current Bellwether pool Plaintiffs). Additionally, through further discovery, certain Plaintiffs may drop out or certain Defendants be dismissed from individual cases due to lack of product ID or other reasons. Therefore, premature winnowing to an unreasonably small number may result in the Parties being left with an inadequate source of representative cases that have been properly worked up for trial.

During the Parties' March 22<sup>nd</sup> conference, Plaintiffs suggested that dismissed cases from among the limited pool of eight be replaced with another case in the larger pool of twenty-eight, with Plaintiff picks being replaced by another Plaintiff pick and Defendant picks by a Defendant pick. Under Plaintiffs' plan, however, little or no workup would have been done in the potential replacement cases. Plaintiffs have not explained how discovery in the replacement cases could be completed by the current discovery deadlines, and certainly not on the same timeline as the original

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cases in the pool, particularly if a case is dismissed months from now. This could result in a very small pool of cases being trial-ready when the Court is ready to proceed with bellwether trials. If the Bellwether pool is prematurely winnowed to eight cases for work-up, it is likely that, as dismissals and substitutions occur even fewer cases will be trial-ready when the Court is ready to proceed with bellwether trials (which could be accelerated if class certification is denied and the class actions do not reach trial). Maintaining the larger pool of twenty-eight through discovery and ensuring a sufficient number of trial cases remain “live” will help remedy these concerns.

Finally, Defendants object to the provision in Plaintiffs’ new proposal calling for the automatic inclusion of the two so-called “joint picks” in the winnowed pool of eight. Defendants would be prejudiced by such a provision. These two cases are in essence Plaintiffs’ picks, as they were part of Plaintiffs’ original DFS selections. These two cases were included in the Bellwether Trial Pool as a result of a compromise between the Parties to avoid waste of the resources expended by the workup of these Plaintiff-picked cases and to ensure that ten Plaintiff depositions could be completed within the deadlines set forth in [CMO 22](#). These are not truly “joint picks” from the docket at large. Notably, six other cases in the pool of 28 were also picked as a result of this compromise and are therefore skewed in favor of Plaintiff. This is another reason Defendants should have input into the final, winnowed selections, rather than blind random selection, in order to account for this imbalance.

Overall, Plaintiffs’ new proposal presents a number of details and complications that are premature, unnecessary, unfair to Defendants, and contradictory to the Parties’ and the Court’s discussions to date. Looking at the bigger picture, it is clear Plaintiffs’ motivation in presenting this new proposal is to revisit the allowable Plaintiff discovery under the Court’s [CMO 23](#), take

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the focus off of the personal injury claims, and to minimize Plaintiffs' obligation to participate in discovery.

However, the Court has already announced that discovery should proceed on the bellwether pool and that the cases will be sequenced for trial by random-selection closer to the trial phase. In fact, Judge Kugler even suggested that discovery could commence on as many as forty bellwether plaintiffs:

I agree with defendants that they should suggest 20 potential plaintiffs so you have a total of 40 plaintiffs, **which you're taking discovery on** for the personal injury cases. Where that leads, I don't know yet. It would certainly be preferable if we're going to do bellwether trials to choose the trials from that 40, but my experience with that has not been satisfactory because you end up with a lot of cases getting dismissed when they're listed for trial. So what I -- what I will do is, I will make random selections if we get to that stage of bellwether trial for that.

[Tr. 11/24/20 CMC at 15:7-15](#) (emphasis added). Judge Kugler wisely recognized that discovery has to proceed on a larger number of cases, given the natural winnowing via dismissals, and that random sequencing for trial is likely necessary, but the Court left open for another day whether there will be any additional "choosing" in the interim.

Additionally, as Defendants have said before, Plaintiffs depositions and their treaters' depositions are certainly necessary and relevant to finalization of Defendants' expert reports and *Daubert* challenges. The Court has also specifically rejected Plaintiffs' repeated argument that workup of individual personal injury cases, or general causation, should be stalled or phased until later. The Court has made clear repeatedly that the personal injury cases and general causation should be worked up on a parallel track along with the consumer class actions, while acknowledging that this would require work and appropriate staffing:

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It is my intention that the November conference, at the end of November, to enter an order governing discovery on the general causation/bodily injury claims. I also agree with defense counsel that there needs to be sometime mid next year, service of expert reports on those issues and *Daubert* hearings, if necessary. So what I'm telling you is, that you need to continue discussing this with the eye towards the November status conference, late November status conference, the Court entering an order governing the discovery on that parallel track. It's going to have to be parallel. We're not taking any resources away from the discovery and all the work that needs to be done that's already scheduled and set up. So sounds to me like you're going to have to get a whole other army of lawyers involved to do that kind of discovery in those other issues, but that's where we're going to go with this in the future.

[Tr. 09/30/20 CMC, 49:13-50:4.](#)

In sum, Plaintiffs' "Bellwether Trial Plan" is merely an effort to end-run around the Court's instruction that discovery and work-up of the agreed-upon personal injury bellwether pool should proceed. To the extent that further winnowing and sequencing needs to occur before trial, a point Defendants do not necessarily dispute, the Parties can continue to meet and confer on those processes and/or the Court can decide at a time closer to trial, once more is known about the pool of twenty-eight and any dismissals or adjustments to the Parties have occurred.

#### **4. Discovery Issues**

##### **a. Hetero**

Defendants Hetero Drugs Ltd. and Hetero Labs Ltd. (collectively, "HLL") have made significant progress in addressing Plaintiffs' concerns regarding its discovery productions. As of Plaintiff's correspondence to HLL transmitted late in the evening on March 29, 2021, Plaintiffs have set forth a narrow list of specific documents outstanding, which HLL is currently locating within its prior productions or will produce to Plaintiffs forthwith.

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Since our last Case Management Conference before Judge Vanaskie on March 24, 2021, HLL has made several supplemental document productions to remedy document deficiency issues and other inquiries raised by Plaintiffs. On March 25, 2021, HLL produced an overlay file to correct metadata deficiencies in a prior document production. The next day, on March 26, 2021, HLL produced “Annexure” documents that were previously deemed non-responsive. That same day, HLL responded to Plaintiffs’ new inquiry regarding litigation hold notices by providing Plaintiffs with a letter setting forth the dates of HLL’s litigation holds and the recipients. Further, on March 26, 2021, HLL provided Plaintiffs with a second letter responding to its other remaining inquiries, setting forth the search conducted by HLL of its electronic databases, as well as information regarding our anticipated production of Batch Records, our investigation into the “surrounding emails” regarding edits to draft SOPs, and information regarding the role of HLL Unit IX. Subsequently, on March 30, 2021, HLL produced its production volume “HLL13” to encompass additional documents that were not previously produced.

Yesterday, March 29, 2021, at 9:40 pm, HLL received correspondence from Plaintiffs setting forth the remaining discovery issues to be addressed. Plaintiffs’ letter included specific questions as well as a list of documents that remain outstanding. HLL is in the process of confirming whether the documents requested are contained in HLL’s prior document productions. To the extent that the documents were not previously produced, HLL will immediately collect same and produce to Plaintiffs in an expedited manner. HLL notes that several categories of documents requested in Plaintiffs’ March 29, 2021 letter were not set forth in Plaintiffs’ prior letters or raised in meet and conferrals with the undersigned Counsel, however HLL is nevertheless endeavoring to locate or produce the documents requested. Plaintiffs’ letter additionally set forth

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areas that have already been addressed by HLL, including production of all Annexure documents previously deemed non-responsive, questions regarding HLL Unit IX, and “surrounding emails.”

Accordingly, HLL is continuing to diligently address all issues raised by Plaintiffs, and the list of open items has narrowed substantially. HLL is amenable to commencing the depositions for which Plaintiffs are prepared to begin based on the substantial number of documents provided to date, and will await Plaintiffs’ indication that they are prepared to proceed.

**b. The Aurobindo Parties**

**(i) Custodial Files from Aurobindo Pharma Ltd.**

Aurobindo Pharma Ltd. has transferred all custodial files via FTP and the data is currently being ingested by their eDiscovery vendor. We will continue to work diligently to review the documents and make a good faith effort to produce them to Plaintiffs’ counsel as soon as possible. Counsel for Aurobindo Pharma Ltd. has offered to meet and confer with Plaintiffs regarding production deadlines. Plaintiffs are unwilling to do so and demand that all custodial files be produced by April 9. Plaintiffs would like this Court to believe that the Aurobindo parties have produced only 46 documents since the issue arose. That is simply not true. The Aurobindo parties have made twelve substantial productions so far this month and another will be made today. This includes 200,104 pages of documents produced by Aurobindo Pharma Ltd. from four custodians, as well as agreements with customers and suppliers, and Standard Operating Procedures. In addition, Aurobindo will produce data from four more custodians by April 1, as agreed to by the parties and presented to the Court during the conference on March 10, 2021. In addition, as discussed further below, Aurobindo Pharma USA, Inc. and Aurolife Pharma LLC have produced over 4,000 documents in March.

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**(ii) Withheld Documents**

Yesterday counsel for the Aurobindo parties had a productive meet and conferral with Plaintiffs' counsel regarding their list of purportedly improperly withheld documents. The Aurobindo parties agreed to produce all documents except for four, including:

1. Auro-MDL 2875-0095192
2. Auro-MDL 2875-0095120
3. Auro-MDL 2875-0097099
4. Auro-MDL 2875-0095119

Nos. 1 and 2 above are duplicates and so are nos. 3 and 4. These documents were properly withheld because they do not relate to the Aurobindo facilities involved in this action or the products at issue. They are documents regarding FDA inspections of third parties who are not involved in this MDL, and they pertain to other products. The Aurobindo parties' position is consistent with the Court's rulings on the marco discovery issues. *See* [ECF 303](#). Plaintiffs have confirmed that this issue is now resolved.

**(iii) Standard Operating Procedures**

The Aurobindo parties also agreed to produce the majority of the additional SOPs Plaintiffs' requested. Plaintiffs' withdrew their request for SOPs: QA852, ZQA020, ZQC054, KQA011, and KQC014. During counsels' meet-and-conferral, Plaintiffs asked several follow up questions regarding the following SOPs, and defense counsel advised that she should have a response for Plaintiffs by tomorrow:

ZQA022 – Site Master File  
ZQA002 – Format Preparation and Numbering System  
ZQC018 – Standards Management  
KQA013 – Creation of user identification user privileges, password policy, log in and log out for document issuance software  
KQA041 – Online Activity Monitoring

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KQC074 – Password Policy  
MF115 – Cleaning of the Manufacturing Corridors, Washrooms, and In-Process  
Staging Area  
MF100 – Cleaning of the Purified Water Room

Plaintiffs confirmed that, pending our responses to their follow-up questions, this dispute can be deemed resolved.

**(iv) Shared Drives and Databases**

We have verified that all shared drives have been searched and we intend to supplement the document productions to the extent there is data responsive to Plaintiffs' requests. Sales and pricing data was produced from the Oracle database in May 2020. Trackwise, LIMS and QAMs are not searchable per se. We offered to meet and confer with Plaintiffs regarding reports that can be generated from those databases. They refused and demanded to speak with Aurobindo's eDiscovery vendor. We told Plaintiffs that we do not believe a call with Aurobindo's vendor is necessary but we are open to discussing this further if Plaintiffs will clarify what information they believe they need from the vendor. Plaintiffs just raised this for the first time via email at 10:39 p.m. EST Thursday, March 25<sup>th</sup>. Accordingly, there is no need for a Court Order allowing Plaintiffs to speak with Aurobindo's vendor as we anticipate that any requests for information are capable of being answered by counsel. Furthermore, Aurobindo is prepared to meet and confer in an effort to provide the information to Plaintiffs' counsel regarding any additional requests.

The Aurobindo parties have agreed to produce the following SOPs on document control:

QA806 – Document Control  
QA019 – Good Documentation Practices  
KQA001 – Good Recording Practices  
ZQA021 – Document Control  
KQC061 – Recording Flow of Quality Control Department Documents



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We told Plaintiffs that we do not believe a call with Aurobindo's vendor is necessary but we are open to discussing this further if Plaintiffs will clarify what information they believe they need from the vendor. Plaintiffs just raised this for the first time via email at 10:39 p.m. EST Thursday, March 25<sup>th</sup>. Accordingly, there is no need for a Court Order allowing Plaintiffs to speak with Aurobindo's vendor as we anticipate that any requests for information are capable of being answered by counsel. Furthermore, Aurobindo is prepared to meet and confer in an effort to provide the information to Plaintiffs' counsel regarding any additional requests.

**(v) Litigation Hold Letters and Data Production Policies**

On Thursday, March 25<sup>th</sup>, Plaintiffs requested Litigation Hold Letters and copies of all document and email retention and/or destruction policies in place from 2014 to the present for all Aurobdino entities. This demand is purportedly based on deposition testimony from Prasad Gorijavolu and Bhradresh Doshi.

Generally, litigation hold letters are not discoverable. *See Major Tours, Inc. v. Colorel*, 2009 U.S. Dist. LEXIS 68128 citing *In re eBay Seller Antitrust Litigation*, No. 07-CV-01882(RS), 2007 U.S. Dist. LEXIS 75498 (N.D. Cal. Oct. 2, 2007) (internal citations omitted). Litigation hold letters become discoverable only upon a preliminary showing of spoliation. *See Major Tours*, 2009 U.S. Dist. LEXIS 75498 at \*7.

Discovery and document production remain ongoing. At present, Plaintiff has provided no evidence to suggest spoliation of relevant evidence. Accordingly, Plaintiffs' requests for Litigation Hold Letters and Data Production Policies are not ripe at this time, particularly as this issue was first raised in the late evening hours of March 25<sup>th</sup>. Should the Court wish to hear further, Aurobindo requests a briefing schedule be set to fully develop and argue this issue.

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**(vi) Privilege Log**

The parties also met and conferred regarding Aurobindo's Privilege Log, and the Aurobindo parties will agree to de-designate the following documents.

1. Auro-MDL 2875-0087312
2. Auro-MDL 2875-0087370
3. Auro-MDL 2875-0103844
4. Auro-MDL 2875 0103845
5. Auro-MDL 2875-0104811
6. Auro-MDL 2875-0104812
7. Auro-MDL 2875-0104843
8. Auro-MDL 2875-0104844
9. Auro-MDL 2875-0104845
10. Auro-MDL 2875-0104877
11. Auro-MDL 2875-0105379
12. Auro-MDL 2875-0106023
13. Auro-MDL 2875-0106024
14. Auro-MDL 2875-0106282
15. Auro-MDL 2875-0106283
16. Auro-MDL 2875-0106285
17. Auro-MDL 2875-0106286
18. Auro-MDL 2875-0106306
19. Auro-MDL 2875-0106307
20. Auro-MDL 2875-0106308
21. Auro-MDL 2875-0106309
22. Auro-MDL 2875-0107385
23. Auro-MDL 2875-0107392

Additionally, the Aurobindo parties agreed that the following documents will be de-designated as to attorney-client privilege but remain subject to work-product.

1. Auro-MDL 2875-0088941
2. Auro-MDL 2875-0103977
3. Auro-MDL 2875-0103979
4. Auro-MDL 2875-0104018
5. Auro-MDL 2875-0104019
6. Auro-MDL 2875-0104020
7. Auro-MDL 2875-0104021

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8. Auro-MDL 2875-0104809
9. Auro-MDL 2875-0104810
10. Auro-MDL 2875-0104914
11. Auro-MDL 2875-0106290
12. Auro-MDL 2875-0106291
13. Auro-MDL 2875-0106292
14. Auro-MDL 2875-0106293
15. Auro-MDL 2875-0106304
16. Auro-MDL 2875-0106329
17. Auro-MDL 2875-0106330
18. Auro-MDL 2875-0106331
19. Auro-MDL 2875-0106332
20. Auro-MDL 2875-0106334
21. Auro-MDL 2875-0106345
22. Auro-MDL 2875-0106336
23. Auro-MDL 2875-0106337
24. Auro-MDL 2875-0107386
25. Auro-MDL 2875-0107387
26. Auro-MDL 2875-0107388
27. Auro-MDL 2875-0107389
28. Auro-MDL 2875-0107390

Despite Aurobindo's good faith efforts to resolve any dispute as to privilege, Plaintiffs have continued to demand that all documents be produced immediately.

Initially, Plaintiffs demand production of all documents deemed subject to attorney-client privilege that include "communications between non-lawyer employees only" unless Aurobindo affirms that any of the authors, senders, recipients, or copyees are attorneys who were rendering legal advice. The law imposes no such requirement. Communications between lay employees remain privileged if such documents assist counsel in the formulation of legal advice. *See In re Riddell Concussion Reduction Litig.*, 2016 U.S. Dist. LEXIS 168457 (D.N.J. December 5, 2016) citing *Westinghouse Elec. Corp. v. Republic of the Philippines*, 951 F.2d 1414, 1424 (3d Cir. 1991) (internal citations omitted). As of this writing, Aurobindo has agreed to de-designate all but 16 of the requested documents as to attorney-client privilege. Each of these sixteen documents contains

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communications intended to facilitate, coordinate, or effectuate legal advice by counsel and are therefore properly withheld.

Plaintiffs next suggest that a series of documents were improperly withheld due to the purported over-inclusion of recipients. Plaintiffs imposed an arbitrary limit of five recipients and demand production of all communications involving six parties or more. This subjective standard ignores the complexities of litigation of this scale and complexity. In an undertaking such as this, participation of multiple parties is essential to obtain and implement sound legal counsel.

Plaintiffs further contend that the involvement of any third-party entity automatically negates confidentiality. Initially, it should be noted that many of the so-called third-party documents referenced by Plaintiffs have been de-designated and will be produced or are being withheld solely as work-product. Of the remaining documents, several do not involve any third-parties. The remaining few involve third-party agents necessary to effectuating legal counsel.

Further, Plaintiffs' position regarding the effect of third-party agents is simply inaccurate. The mere involvement of a third-party does not eliminate confidentiality. "When disclosure to a third-party is necessary for the client to obtain informed legal advice, courts have recognized exceptions to the rule that disclosure waives the attorney-client privilege." *In re Riddell*, 2016 U.S. Dist. LEXIS at \*14 quoting *Westinghouse Elec. Corp.*, 951 F.2d 1424 (internal citations omitted). These documents are therefore properly withheld.

Plaintiff next alleges that documents sheltered by the work-product doctrine "appear to be nothing other than ordinary-course business documents [sic]." As set forth in detail above, Aurobindo has de-designated several documents. Additionally, Aurobindo has revised its privilege log to further certify that the remaining documents were prepared in anticipation of imminent litigation. In light of the allegations underlying this multi-district litigation, litigation was

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reasonably foreseeable. Context establishes the clear application of the work product doctrine to these items. Courts have considered factors such as severity of injury in ascertaining whether a document is properly designated as work product. *See Basinger v. Glacier Carriers, Inc.*, 107 F.R.D. 771 (M.D. Pa. October 22, 1985). Allegations of severe illness or injury lead to a reasonable inference that litigation is imminent. Similarly, timing is often considered in ascertaining the application of work-product. The documents at issue are not remote to litigation. Litigation was not a “remote prospect” at the time these documents were created. In fact, claims had already begun at the time of their inception. Thus, these documents are properly shielded by work product.

Finally, Plaintiffs insist that work product protection extends solely to documents with a demonstrable “link to an attorney.” This supposition is wholly unsupported by law. The Federal Rules of Civil Procedure specifically set forth that “a party may not discover documents and tangible things that are *prepared in anticipation of litigation or for trial by or for another party or its representative* (including the other party’s attorney . . . .” Fed. R. Civ. P. 26(b)(3)(A). The rule is inclusive of attorneys and cannot reasonably be interpreted as exclusive to attorneys. The remaining documents are clearly subject to work product and therefore precluded from disclosure.

**c. Mylan**

There are two outstanding discovery disputes between Mylan and Plaintiffs. The first relates to the 4,200 documents that Plaintiffs have challenged as improperly withheld. The second relates to Plaintiffs’ request for FDA correspondence related to the Mylan’s Unit 7 facility. With regard to the 4,200 documents, Mylan has submitted the requested random sample set of documents to the Court for its *in camera* review. With respect to the Unit 7 discovery issue, the matter was fully argued during the March 24, 2021 CMC, and the parties are awaiting the Court’s determination.

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**5. Joint Stipulation Regarding Dismissal of Torrent Private Ltd.**

On November 13, 2020, Torrent filed a joint stipulation with Plaintiffs regarding the dismissal of Torrent Private Limited ([ECF 630](#)). Torrent respectfully requests that the Court enter this joint stipulation.

**6. Protocol for Dismissal of Certain Defendants Without Prejudice**

On March 4, 2021, an agreed upon Protocol for Dismissal of Certain Defendants Without Prejudice and Amended Stipulated Order regarding Dismissal of Peripheral Defendants to Include Losartan and Irbesartan was sent to the Court for entry. To date, the Orders have not been entered therefore Defendants request that entry occurs or if the Court has questions, Defendants will be prepared to discuss.

**7. Plaintiff Fact Sheet Show-Cause Submission**

**Cases Addressed at the February 24, 2021 Case Management Conference:**

Defendants note that the Court issued six show cause orders returnable at the March 24, 2021 Case Management Conference.

The issues in two cases have been resolved and the order to show cause may be withdrawn:

- Patterson, Linda – 20-cv-14605
- Gibson, James – 20-cv-12117

These four cases remain subject to an order to show cause at the March 24, 2021 Case Management Conference for failure to substantially complete a PFS:

	<b>Plaintiff</b>	<b>Civil Action No.</b>	<b>Law Firm</b>	<b>Deficiencies</b>	<b>Deficiency Notice Sent</b>
1.	Medrano, Rene	20-cv-12099	Fears Nachawati	I.C.1 - Plaintiff produced pharmacy records from Mid Valley Pharmacy that	12/10/20

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				<p>demonstrate use of Amlodipine, however Plaintiff has identified use of Amlodipine/Valsartan in the PFS. Please produce proof of use of the identified Amlodipine/Valsartan product. Also, the produced pharmacy records do not include NDC codes. Please produce pharmacy records or other documentation that includes NDC codes. In addition, an authorization for Mid Valley Pharmacy was not provided.</p> <p>I.C.4 – Failed to provide the NDC Code for the second identified product.</p> <p>I.D.1 - Plaintiff did not produce medical records for the following identified health care provider: Dr. Habib Ghaddar. Please produce complete medical records for the foregoing identified health care provider.</p> <p>II.D.4.c - Failed to provide the dates of exposure in Plaintiff's diet including red and/or processed meats. Plaintiff's answer is cut off on the PFS form in the Third Amended PFS. Please provide the complete answer and include a supplemental page if the answer will not fit on the PFS form.</p> <p>III.G.a – III.G.c - Plaintiff failed to provide substantive responses to the requests regarding the medical expenses he is seeking recovery for. Plaintiff indicated in the PFS that billing records have been requested. Please provide the medical expense information and the billing records as they become available.</p> <p>XI.A.1 – Failed to provide healthcare authorizations for the following: Dr. Ricardo Lerma; Benjamin Salinas; Pamela Lopez FNP; Dr. David E. Yardley; Dr. Christopher Wood; Dr. Debra Woloski; Dr. Habib Ghaddar; Mid Valley Pharmacy; Walgreens; Walmart.</p>	
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				<p>XI.A.7 – Plaintiff produced a mental health records authorization for Jose Igoa, MD, however the produced mental health records authorization is dated. Please produce a properly executed and undated mental health records authorization for Jose Igoa, MD.</p> <p>XI.B.2 - No pharmacy records were produced for the following identified pharmacies: Walgreens or Walmart.</p> <p>XI.B.9 - No photographs of the packaging or labeling for the identified Amlodipine Valsartan product was produced. Plaintiff only produced photographs of labeling for a Losartan product.</p> <p>XI.B.18 - No medical expense records were produced. Plaintiff indicated in the PFS that billing records have been requested. Please produce the billing records as they become available.</p>	
2.	Greenleaf, Robert	20-cv-8785	Hollis Law	No PFS Filed	PFS Due - 11/28/20
3.	Jackson, Rickey	20-cv-14927	Levin Papantonio	No PFS Filed	PFS Due - 12/22/20
4.	Newcombe, Sonja	20-cv-10274	Levin Papantonio	No PFS Filed	PFS Due - 8/11/20

**Second Listing Cases – Order to Show Cause Requested:**

Pursuant to [CMO 16](#), the Plaintiff Fact Sheets in the below cases are substantially incomplete and contain core deficiencies. Each of these three cases were previously listed on the agenda for a prior CMC. Defendants provided a list including these cases and identified deficiencies to Plaintiffs’ leadership counsel for distribution on March 16, 2021, met and conferred



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with Plaintiffs' counsel on March 19, 2021, and have been available for further meet and confers as needed. Accordingly, Defendants request that an Order to Show Cause be entered in each of these cases, returnable at the next case management conference, as to why the case should not be dismissed.

Defense counsel will be prepared to address the individual issues with respect to each of these cases, to the extent necessary, during the March 24, 2021 Case Management Conference:

	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Notice Sent
1.	Williams, Naomi	20-CV- 08772	Levin Papantonio	No PFS Filed	Due - 09/18/2020

**First Listing Cases – Remaining Core Deficiencies:**

The following Plaintiff Fact Sheets contains core deficiencies which remain unresolved. Defendants provided a list including these cases and identified deficiencies to Plaintiffs on March 16, 2021 and met and conferred with Plaintiffs' counsel on March 19, 2021 and have been available for further meet and confers as needed. This is the first time these cases have been listed on this agenda. Accordingly, Defendants are not requesting orders to show cause with respect to any of the below cases at this time and will continue to meet and confer to resolve these deficiencies.

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	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Notice Sent
1.	Cunningham, Kristine	2020 - CV-12812	Brown LLC	HIPAA authorizations need to be filled out to providers listed in PFS – not blank.	2/18/21
2.	Williams, Taffnie	2020 - CV-20380	The Donahey Firm	No authorizations. PFS substantially incomplete.	3/12/21
3.	Day, Peter Townsend	20-cv-19777	Rheingold Giuffra Ruffo Plotkin LLP	<p>III. H Failure to provide response regarding specialized economic damages.</p> <p>IV. E Failure to provide response regarding witnesses.</p> <p>V. A, C Failure to provide responses regarding weight.</p> <p>VI. B Failure to provide any response regarding OTC medications.</p> <p>XI. A. 1 Failure to provide completed authorizations for each healthcare provider.</p> <p>XI. A. 6 Failure to provide completed insurance authorization.</p> <p>XII Failure to provide executed Declaration page.</p>	2/29/21
4.	Mundy, Gwendolyn	20-cv-08285	Watts Guerra LLP	III. G. C Failure to itemize or provide amount of medical expense(s).	2/26/21
5.	Cassarar, Ronald	20-cv-08774	Hollis Law Firm	<p>I. C. 16 Failure to provide records demonstrating Product ID.</p> <p>XII Failure to provide dated Declaration page.</p>	2/19/21

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6.	Stewart, Pamela	20-cv- 03788	Erlanger Law Firm PLLC	<p>I.D.1 - Failed to attach records.</p> <p>Medical records in your possession demonstrating alleged injury, this is a personal injury action.</p> <p>III.G.a - Failed to respond.</p> <p>Medical expenses.</p> <p>V.G.1 - Failed to respond.</p> <p>Section V.G.</p> <p>XI.A.1 - Failed to provide properly signed, undated, and completed authorization.</p> <p>XI.A.4 - Failed to provide properly signed, undated, and completed authorization.</p> <p>XI.A.5 - Failed to provide properly signed, undated, and completed authorization.</p> <p>XII - Failed to provide signed and dated, declaration.</p>	12/22/20
7.	Ragland, Arnold	10-cv- 04363	Watts Guerra, LLP	<p>I.E - Failed to respond.</p> <p>Section E – Representative information.</p> <p>II.C-K - Failed to respond.</p> <p>Sections II.C, D, G to J.</p> <p>III.F - Failed to respond.</p> <p>Section III.F</p> <p>IV.E - Failed to respond.</p> <p>- Witnesses</p>	7/6/20

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				<p>XI.A.1, 6 - Failed to provide undated, completed and signed authorizations.</p> <p>XII - Failed attach completed, dated and signed declarations.</p>	
8.	Wetzel, Winfield	2020- CV- 16130	Hollis Law Firm, P.A.	<p>III.A.1.b – Plaintiff still failed to provide how he has managed or treated his hypertension after discontinuing use of Valsartan products</p> <p>XI.B.2 – Plaintiff only produced eight (8) pages of medical records. Please produce Plaintiff’s complete medical records that are relevant to Plaintiff’s treatment for the alleged injury(ies) that he claims resulted from Valsartan usage. Also, no pharmacy records were produced for Giant Pharmacy. The produced pharmacy records that are titled as “Pharmacy Records – 2020.10.20 Giant_Food_PharmacyWetzel_Winfield” in Centrality are actually pharmacy records from Martin Pharmacy.</p>	2/10/21
9.	Futch, John	2020- CV- 16139	Hollis Law Firm, P.A.	<p>III.A.1.b – Plaintiff states the he managed his hypertension with the use of Irebsartan and Losartan after discontinuing Valsartan products in the Amended PFS. However, the produced pharmacy records include usage of Irbesartan by the Plaintiff and do not include any usage of Losartan. Please clarify and supplement the response to this request.</p> <p>XI.B.2 – No medical records were produced for the identified cancer date, being January 31, 2018. Also, no medical records were produced for the physician who prescribed Valsartan for the Plaintiff, being Gregory Glance, MD. No pharmacy records were produced for</p>	2/17/21

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				the following identified pharmacy: Moses Cone Hospital Pharmacy.	
10.	Canfara, Michael- Est. of (Mashrique, P.)	2020- CV- 1834	Stark & Stark	No authorizations. PFS substantially incomplete.	02/09/2021

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

cc: Adam Slater, Esq. (*via email, for distribution to Plaintiffs' Counsel*)  
Jessica Priselac, Esq. (*via email, for distribution to Defendants' Counsel*)  
Sarah Johnston, Esq. (*via email*)  
Jeffrey Geoppinger, Esq. (*via email*)  
Lori G. Cohen, Esq. (*via email*)  
Clem C. Trischler, Esq. (*via email*)